Rec'd PCT/PTO 01 APR 2005 #2
PCT/AU03/01289
10/530152

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J R Yabsley

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<u>SUPPORT AND SALES</u>

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AUSTRALIA

Patents Act 1990

Spinemed Australia Pty Limited

PROVISIONAL SPECIFICATION

Invention Title:

Intervertebral disc restoration

The invention is described in the following statement:

Technical Field

The present invention relates to a nucleus pulposus replacement device, a method for implanting a nucleus pulposus replacement device, a delivery device for implanting a nucleus pulposus replacement device, and a method of determining the geometric boundaries of the nucleus of an intervertebral disc.

Background Art

The human intervertebral disc (IVD) is a structure composed of a complex arrangement of various connective tissues. The structure of the IVD allows for its role in the effect of a functioning spinal column. Degeneration of the IVD is a consequence of aging and may begin as early as the first decade of life in males and the second decade in females. Disc degeneration plays a significant role in the aetiology of nucleus pulposus herniation, spinal stenosis and segmental spinal stability. Furthermore, IVD degeneration is implicated as a causative factor in mechanical lower back pain.

Over the years, there have been several suggestions and techniques relating to the development of prosthetic IVD replacement devices. Such devices include replacement of the entire intervertebral disc, and replacement of the nucleus pulposus only. Other methods of treatment include therapies for degenerated discs such as fusion and discectomy. Artificial devices are intended to restore or preserve the natural biomechanics of the intervertebral segment and to reduce further degeneration of adjacent levels of the spine.

Devices to replace the entire intervertebral disc include mechanical fixation devices which preserve the intersegmental stability using metallic end plates affixed to adjacent vertebra and an elastomeric rubber "nucleus" between the end plates. Other type of devices include "metal on metal" prostheses extending across adjacent vertebra.

Nucleus pulposus replacement devices involve substitution or augmentation of the nucleus pulposus in the event of IVD degeneration with normal annular architecture. Such devices include a prosthetic disc nucleus (eg. The PDN™ of RayMedica Inc., Minneapolis, MN), consisting of hyaluronic

acid (hydroscopic gel) within a semi-permeable membrane that is enclosed in a woven jacket. A pair of these devices is inserted per level of the spine and, with time, an increased water content of the devices from absorption results in the volume of the devices expanding. Another such nucleus pulposus replacement device, is the Aquarelle™ Hydrogel Disc Nucleus (Stryker Howmedica Osteonics, Rutherford, NJ). This device consists of a hydrogel disc nucleus which is inserted, using instrumentation, into the intervertebral disc via a hole in the annulus, the hole having a cross-sectional area approximately one-quarter of that of the implant. The implant is composed of polyvinyl alcohol and water, its water content being high at intradiscal pressures found in the human lumbar spine. This property assists the implant to have a relatively low modulus of elasticity which allows it to conform to the vertebral end plates of the adjacent vertebra.

The present inventor has identified short comings within the prior art and has developed a system which seeks to alleviate some of the short failings.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

In a first aspect, the present invention is a nucleus pulposus replacement device, the device comprising:

a non-constrained body of material introducible into and positionable within an annulus of an intervertebral disc of a subject;

wherein, following introduction into the annulus, the body of material undergoes a change from a first state to at least one second state such that when in said second state, the body of material is constrained within the annulus of the intervertebral disc.

In one embodiment, the body of material can substantially engage with and conform to the internal boundaries of the annulus of the intervertebral disc.

In another embodiment of the first aspect, the body of the device is made from a material having mechanical and visco-elastic properties suitable for structural support and load dampening in a spinal column of a subject.

In a still further embodiment of the first aspect, the device further comprises a non load-bearing membrane located at the periphery of the body of material, wherein the membrane is impermeable to the body of material.

Preferably, the material of the body is made of a silicone-based material. The material can be configured such that it changes from the first state to at least the second state cures after being implanted within the annulus of the intervertebral disc of the subject. In one embodiment, the body of material cures following implantation.

The device may be used to deliver bioactive substances to the annulus of the intervertebral disc of the subject. The bioactive substances may be substances which induce cell growth and/or cell reproduction.

In another embodiment of the first aspect, the device may be used as a drug delivery means for active and/or prophylactic treatment at the site of implantation.

In yet another embodiment, the device may include a radioactive substance and/or radiopaque marker for monitoring by X-ray postoperatively. Examples of such radiopaque marking and monitoring materials include barium sulphate and zinc oxide.

In a second aspect, the present invention is a method of replacing the nucleus pulposus of an intervertebral disc of a subject using the device of the first aspect, the method comprising the steps of:

(i) ablating the nuclear space of an intervertebral disc of a subject through an incision in an annulus of the intervertebral disc;

(ii) distracting the intervertebral disc;

(iii) introducing the body of material into the ablated nuclear space; and

(iv) allowing or causing the body of material to change from its first state to its said at least one second state such that it is constrained within the annulus of the intervertebral disc

In one embodiment of the second aspect, the incision through the annulus of the intervertebral disc is made through surgical approaches including a posterior-lateral approach, and an anterior approach, to the disc.

In another embodiment of the second aspect, the intervertebral disc can be distracted by way of an expansion means and/or by conventional traction. Preferably, the intervertebral disc is distracted by way of an expansion means passing through the incision in the annulus of the intervertebral disc and into the ablated nuclear space.

In a further embodiment of the second aspect, the expansion means used for step (ii) is a balloon device. The balloon device is preferably inflated by a fluid so as to distract the intervertebral disc. The fluid used to expand the balloon device is preferably biocompatible. Examples of suitable fluids include saline, PBS and sterile water.

In another embodiment of the second aspect, the method can include a further step between steps (i) and (ii) wherein the nuclear space is irrigated so as to remove any debris, bone fragments and/or loose tissue.

In a further embodiment of the second aspect, the balloon expansion means can include radiopaque markers which allow the position of the balloon to be monitored by an imaging means, such as X-ray, and allow the pre-screening of disc placement.

In a still further embodiment, after the intervertebral disc has been distracted by the balloon expansion means, the balloon is preferably removed from the nuclear space. As a safety precaution, the nuclear space may then be injected with dilute barium sulphate-saline solution so as to determine if there is a leak into the spinal column.

In one embodiment, the body of material can be introduced into the nuclear space of an intervertebral disc of a subject using the delivery device as defined herein.

According to a third aspect, the present invention is the use of a silicone-based substance for the manufacture of a nucleus pulposus replacement device for the treatment of degenerative disc disease in the spine of a human being.

In this aspect, the nucleus pulposus replacement device can have one or more features according to the first aspect of the invention defined herein.

According to a fourth aspect, the present invention is a delivery device for implanting the device of the first aspect within the annulus of the intervertebral disc of a subject, the delivery device comprising:

a delivery device having a first end for the delivery of the body of material into the annulus whilst the material is in the first state; and

a disengagement means located at said first end of the delivery device;

wherein the disengagement means releases the delivery device from the body of material following delivery of the device into the annulus.

In one embodiment of the fourth aspect, the disengagement means is a crimping means for disengaging the delivery device from the body of material when the material has changed into said at least one second state.

In a further embodiment of the fourth aspect, the delivery device further comprises a flow restrictor which allows the body of material to readily pass through the delivery device and through the disengagement means but which

inhibits the material from flowing in the opposite direction and back into the delivery device.

In a still further embodiment of the fourth aspect, the delivery device further comprises a non load-bearing expandable membrane. The membrane is preferably located adjacent the disengagement means and is positionable about the periphery of the body of material. The membrane is preferably impermeable to the body of material and remains about the body of material upon disengagement of the body of material from the delivery device by the disengagement means.

According to a fifth aspect, the present invention is an intervertebral disc distraction device comprising:

an elongate delivery member; and

an expandable distraction member.

In this aspect, the expandable distraction device can be a balloon device that is expandable by a pressurised fluid. The balloon device is preferably inflated by a fluid so as to distract the intervertebral disc. The fluid used to expand the balloon device is preferably biocompatible. Examples of suitable fluids include saline, PBS and sterile water. More preferably, the expandable distraction member comprises radiographic markers on its periphery for detection using radiographic techniques.

According to a sixth aspect, the present invention is a device for mapping the interior of the nuclear space of an intervertebral disc of a subject, the device comprising:

a transmitter means variably positionable within the nuclear space of the intervertebral disc that outputs a signal;

a receiver means capable of receiving the signal of the transmitter means; and

a processor means that processes the received signal and provides an output indicative of the position of the transmitter means relative to the receiver means.

In an embodiment of the sixth aspect, the device can further comprise a first optical camera for imaging the interior of the nuclear space of the intervertebral disc of the subject. Still further, the device preferably includes a second optical camera that is movable relative to the first optical camera and/or the receiver means. The second optical camera can preferably at least image the periphery of the nuclear space of the intervertebral disc of the subject. In a further embodiment, the second optical camera is preferably movable relative to the first optical camera, with the location and orientation of the second optical camera in the nuclear space being viewable by the first optical camera.

In one embodiment, the first and/or second camera can be a video camera. The video camera can be an analog or digital camera.

According to a seventh aspect, the present invention is a device for imaging the nuclear space of an intervertebral disc of a subject, the device comprising:

a first optical camera for imaging the interior of the nuclear space of the intervertebral disc of the subject; and

a second optical camera that is movable relative to the first optical camera and which images at least the periphery of the nuclear space of the intervertebral disc of the subject;

wherein the location and orientation of the second optical camera is imageable by the first optical camera.

In an embodiment of the seventh aspect, the device can further include a transmitter means variably positionable within the nuclear space of the intervertebral disc, a receiver means, and a processor means, wherein the transmitter means outputs a signal that is detectable by the receiver means and which os processed by the processor means to allow determination of the position of the transmitter means within the nuclear space.

In a further embodiment of both the sixth and seventh aspects, the device can further include a tissue ablation means for ablating the core of the intervertebral disc. Preferably, the tissue ablation means is at least movable relative to the first optical camera.

According to an eighth aspect, the present invention is a device for ablating the core of an intervertebral disc of a subject, the devise comprising:

a first optical camera for imaging the interior of the nuclear space of the intervertebral disc of the subject;

a tissue ablation means for ablating the core of the intervertebral disc, the tissue ablation means being movable relative to the first optical camera; and

a second optical camera affixed adjacent to the tissue ablation means;

wherein the tissue adjacent the ablation means is imageable by the second optical camera and the position and orientation of the ablation means is imageable by the first optical camera.

In an embodiment of the eighth aspect, the device can further comprise a transmitter means variably positionable within the nuclear space of the intervertebral disc, a receiver means, and a processor means, wherein the transmitter means outputs a signal to the receiver means such that the processor means can determine the position of the transmitter means relative to the receiver means.

In a further embodiment of the sixth, seventh and eighth aspects, the receiver means can be located within the nuclear space of the intervertebral disc when the device is in use. Preferably, the transmitter means is a light and/or heat emitting device and the receiver means is an infra-red light and/or heat detection device.

In another embodiment of the sixth, seventh and eighth aspects, the second optical camera is an arthroscope having the imaging portion located at a distal end thereof. Preferably, the arthroscope is flexible. The ablation device is preferably located adjacent to the distal end of the arthroscope. Preferably, the ablation device is a radio-frequency ablation device.

In a still further embodiment of the sixth, seventh and eighth aspects, the transmitter means is a heat or light source that outputs infra-red radiation and is located adjacent to the imaging portion of the arthroscope. Preferably, the transmitter means is user operable, and transmits a signal to the receiver

means such that the three-dimensional position of the transmitter means is communicated to the receiver means.

In yet still a further embodiment of the sixth, seventh and eighth aspects, the device can further comprise an illumination source for illuminating at least a portion of the intervertebral space.

According to a ninth aspect, the present invention is a system for determining at least some of the geometry of the nuclear space of the intervertebral disc of a subject, the system comprising:

(a) a transmitter means variably positionable within the nuclear space of the intervertebral disc and which outputs a signal;

(b) a receiver means that detects the signal of the transmitter means and provides an output corresponding to said detection; and

(c) a processor means that receives and processes the output of the receiver means to map the nuclear space.

In a preferred embodiment of the above aspects, the processor means preferably comprises a computer that can determine the position of the transmitter means in three-dimensional space and so develop a map of that space.

In an embodiment of the ninth aspect, the system can further include an ablation means for ablating the core of the intervertebral disc. Preferably, the ablation means is a radio-frequency type ablation device.

In a still further embodiment of the present aspect, the system can further comprise a first optical camera for imaging the interior of the nuclear space of the intervertebral disc of the subject. Still further, the system can include a second optical camera affixed adjacent to the tissue ablation means, wherein the tissue adjacent the ablation means is imageable by the second optical camera and the position and orientation of the ablation means is imageable by the first optical camera.

In a preferred embodiment of the present aspect, the system further comprises a monitoring system, whereby the image from the first optical

camera and at least the image from the second optical camera can be displayed simultaneously or individually. Preferably the system further provides a means of displaying an image of the intervertebral disc obtained using imaging techniques such as MRI, CT and X-ray. More preferably, the system provides a means for overlaying an earlier obtained image (such as an X-ray, CT or MRI scan) with the map of the core developed by use of the transmitter and receiver means of the system. This allows the region of the core of the intervertebral disc that is being ablated to be monitored and compared with respect to the earlier obtained image.

Still more preferably, the system can provide the geometric parameters of the core of the intervertebral disc for sizing of disc restoration prostheses.

According to a tenth aspect, the present invention is a method for mapping the periphery of the nuclear space of the intervertebral disc of a subject, the method comprising the steps of:

(i) transmitting at least one signal indicative of a position of an internal peripheral portion of the nuclear space, the signal being transmitted from within the nuclear space; and

(ii) determining the position of the internal peripheral portion of the nuclear space from the transmitted signal.

In a first embodiment of the tenth aspect, the transmitted signal is an infra-red radiation signal, with an infra-red receiver means located within the nuclear space being used to detect the transmitted signal.

In a second embodiment of the present aspect, the at least one signal can be received by a receiver means and processed by a computer processor, the computer processor then developing a three-dimensional representation of the periphery of the nuclear space.

In a further embodiment of the present aspect, the method can further include a step of ablating at least a portion of the core of the nuclear space.

Preferably, the core of the nuclear space is ablated by radio-frequency energy. The step of ablating can be performed repeatably with step (i) of the

method being repeated to allow monitoring of the change in the ablated area during the procedure.

In another embodiment of the present aspect, the method can further include a step of overlaying the map provided by the computer processor with an earlier obtained image of the nuclear space. Preferably, the earlier image is obtained by X-ray, CT or MRI imaging techniques.

In a preferred embodiment of the present aspect, the method can further provide a comparison of the earlier obtained image of the nuclear space with the map of the ablated nuclear space provided by the computer processor. Comparison may be made at least partially during or after ablation of the nuclear space.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Figure 1 shows a superior-transverse view through the intervertebral disc of a subject;

Figure 2 shows an anterior view of a disco-vertebral joint of a subject;

Figure 3 shows a sectional view of an annular device;

Figure 4 shows a sectional view of a vertebral distraction device;

Figures 5(i) to 5(v) show steps in annulating and distracting the intervertebral disc of a subject;

Figures 6(i) to 6(iii) are superior-transverse views of implantation of a nucleus pulposus replacement device using a delivery device according to the present invention;

Figure 7 depicts an example of a device for providing an interior map of the nuclear space of an intervertebral disc;

Figure 8 depicts the use of the device of Figure 7; and

Figure 9 is a flow chart of a system of determining the geometry of the nuclear space of an intervertebral disc.

Detailed Description of the Drawings

Figure 1 depicts the annular wall 2 of an intervertebral disc 3 of a subject. A vertebra of the subject is depicted as item 1. The nucleus 10 of the intervertebral disc 3 is located within the annular wall 2.

Figure 2 shows the intervertebral disc 3 of a subject located between two adjacent vertebrae 1 of the subject. The nucleus 10 of the inter vertebral disc 3 is bounded by the vertebrae 1 and the annular wall 2.

Figure 3 is a sectional view of an annulatory device 20 for annulating the annular wall 2 of the intervertebral disc 3 of the subject. A localiser pin 21 is centrally positioned in the annulatory device 20. A trocar member 22 concentrically surrounds the localiser pin 21. An annulatory member 23 is located concentrically around the trocar member 22. The localising pin 21, trocar member 22 and the annulatory member 23 are in slidable engagement relative to each other.

In the depicted example of the annulatory device, the localiser pin 21 is formed of a biocompatible material, such as stainless steel and has a diameter of about 1.5 mm. The trocar member 22 has a distal end diameter of about 1.55mm such that the localiser member 21 can slide within the trocar member 22. The outer diameter of the trocar member 22 is preferably about 3.5 mm. The distal end of the trocar member 22 preferably has a serrated edge such that it can engage fixedly with the outer surface of the annular wall of the intervertebral disc of a subject without dislodging therefrom. The annulatory member 23 also has a cutting edge at the distal end and has an outer diameter of about 4.5 mm. The inner diameter of the annulatory member 23 is slightly

greater than the outer diameter of the trocar device such that sliding engagement is achieved.

The distraction device 30, as shown in Figure 4, can have an elongate delivery member 31 and an inflatable distraction member 32. Preferably, the inflatable distraction member 32 is an inflatable balloon device that is inflatable by a pressurised liquid. Preferably, the liquid used is a bio-inert material including saline and physiological fluid. Included on the periphery of the inflatable distraction member 32 are a plurality of radiopaque markers 33. The radiopaque markers 33 can be metallic or a metallic compound.

Figures 5(i) to 5(v) depict one example of the use of the annulatory device 20 of Figure 3 and the use of the intervertebral disc distraction device. Figure 5(i) depicts how the annulatory device 10 of Figure 1 is engaged, in use, with the intervertebral disc 3 of a subject using a posterio-lateral surgical approach. Other approaches can be utilised. The trocar member 22 and the annulatory device 23 engage with the outer surface of the annular wall 2 of the intervertebral disc 3. The localiser pin 21 is initially used to locate the position at which the intervertebral disc 3 is to be annulated. Once the localiser pin 21 is in position and the annular wall 2 is perforated by the localiser pin 21, the trocar member 22 and the annulation member 23 are guided to the outer surface of the annular wall 2 using the localiser pin such that the trocar member 22 and the annulation member 23 are located as shown in Figure 5(i).

The annulation member 23 is then used to annulate the annular wall 2 as shown in Figure 5(ii). The cutting surface located at the distal end of the annulation member 23 allows cutting of the annular wall 2. The trocar member 22, by being engaged with the outer surface of the annular wall 2, provides support for the annulation member 23 whist the annular wall 2 is cut.

A working cannula 24 having an inner diameter slightly greater than the outer diameter of the annulation member 23 is then engaged with the outer surface of the annular wall 2 as shown in Figure 5(ii). The annulation member 23 is used to guide the working cannula 24 into a position of engagement with the outer surface of the annular wall 2. The working cannula 24 can have engagement means for engaging with the outer surface of the annular wall 2.

Such engagement means include pins, barbs or spikes. The localiser pin 21 and the trocar member 22 may be removed from the subject before or after the working cannula 24 is engaged with the outer surface of the annular wall 2. Once the working cannula 24 is engaged, the annulation device can be withdrawn from the subject through the working cannula 24. A stabilisation device 25 can be used external of the subject to stabilise the working cannula 24 (see Fig. 5(iii)).

An ablation device 40 is then inserted into the nucleus 10 of the intervertebral disc 3 through the working cannula as shown in Figure 5(iii). The ablation device 40 is used to ablate the nucleus 10 of the intervertebral disc 3. The ablation device 40 can be for example a mechanical ablation device or a radio-frequency tissue ablation device. Once ablation is complete, the ablated nucleus 10 can be lavarged using saline or a physiological fluid. A radiopaque die for example dilute barium sulphate solution can be injected into the nucleus 10 and the subject scanned using radiographic techniques to determine the integrity of the annulus 22 and to determine if any leakage into the spinal canal of the subject has occurred. Arthroscopic techniques can also be employed through the working cannula 24 for inspection of the nucleus 10.

The intervertebral space between the vertebrae 1 of the subject is distracted following ablation of the nucleus 10. Distraction can be traction and/or internal distraction using the distraction device as shown in Figure 4. The ablation device 40 is withdrawn from the subject through the working cannula 24 and the distraction member 32 of the distraction device is inserted into the ablated nucleus through the working cannula 24, with the delivery member 31 extending through the working cannula 24 and out of the subject as shown in Figure 5(iv).

Pressurised fluid, for example saline solution, is injected through the delivery member 32 and into the distraction member 31, and pressurised for a period of time such the distraction of the vertebrae 1 adjacent the intervertebral disc 3 occurs. The subject can be imaged using radiographic techniques whilst the distraction member is expanded so as to determine the geometric parameters of the nucleus 10 of the intervertebral disc 3, as shown in Figure 5(v).

Figure 6(i) depicts the implantation a nucleus pulposus replacement device according to the present invention within the nucleus 10 of the intervertebral disc 3 of a subject. Implantation of the device can follow the steps of the procedure as discussed with respect to Figure 5.

A delivery device 41 is inserted within a working cannula 24, to the nuclear space 10 of the intervertebral disc 3. The material 50 from which the nucleus replacement device is formed is then injected through the delivery device 41 and into the nucleus 10 of the intervertebral disc 3, whilst the material 50 is in a first state suitable for injection. The material 50 can them conform substantially to the interior of the nucleus 10. The material 50 preferably has mechanical and visco-elastic properties suitable for pulposus replacement. An example of such a material 50 is a silicone-based material. Preferably, the material is self-curing by which the material changes to a second state having mechanical properties suitable for pulposus replacement.

Upon curing of the material 50, a disengagement means 42 of the delivery device 41 allows the delivery device 41 to be disengaged from the cured material 50 and withdrawn through the working cannula 24. Remaining within the nucleus 10 is the nucleus pulposus replacement device, substantially conforming to and constrained by the geometric boundaries of the nucleus, formed of the cured material 50.

Figure 6(ii) shows a further example of implantation of the nuclear pulposus device, the device further comprising an outer membrane 43. During implantation, the membrane is fluidly attached to the delivery device 41 at the disengagement member. The delivery device 41 is inserted into the working cannula 24 such that the membrane 43 is located within the nucleus of the intervertebral disc 10. The material 50 from which the nucleus pulposus replacement device is formed from is delivered in the same manner as described in Figure 6(i). Upon injection and at least a degree of pressurisation, the membrane 43 substantially conforms with the inner surface of the nucleus 10. Upon curing, the delivery device 41 is disengaged from the material 50 and the membrane 43 and removed from the working cannula 24.

Figure 6(iii) shows an example of removal of the delivery device 41, following curing of the material 50. In this example, the delivery means is disengaged from the material 50 and the membrane by rotating the delivery device 40 within working cannula 24 and withdrawing the delivery device 41 through the working cannula 24.

Figure 7 depicts an example of a device 60 that can be used to generate an interior map of the nuclear space of an intervertebral disc 3 of a subject. The device 60 includes a transmitter 63 and a receiver 64. The transmitter 63 is located at the distal end of a flexible portion 61 of the device 60. The position and orientation of the flexible portion 61 is controllable by the surgeon from a position external the body of the subject. The transmitter 63 transmits a signal to the receiver 64 that allows determination of the position of the transmitter relative to the receiver 64. An example of a suitable transmission mode is infra-red. In this example, the transmitter 63 is in direct line-of-sight from the receiver 64. The device 60 further includes an optical camera 62 located at the distal end of the flexible portion 61, and a second optical camera 65. A light source 67 is also included to allow imaging by the optical camera in the visible spectrum.

An ablation device 66 may also be also located at the distal end of the flexible portion 61. An example of a suitable ablation device includes a radio-frequency type probe.

Figure 8 depicts one example of the use of the device of Figure 7. The device can be used for ablating the nucleus of the intervertebral disc of a subject and mapping the periphery of the nuclear space 10. The device 60 is inserted within the nuclear space 10 of the intervertebral disc of a subject through a working cannula 24. Examples of suitable surgical approaches include posterior-lateral approach and an anterior approach.

An optical camera 62 is located at the distal end of the flexible portion 61. The ablation device 66 is used to ablate the interior of the nuclear space 10. The region of the nuclear space at which ablation occurs can be imaged by the optical camera 62 and so provide an output visible to the surgeon during the procedure. The optical camera 65 allows for overall imaging of the distal

end of the device 60 and the visual monitoring of the ablation device 66 during ablation assists in ensuring appropriate use of the ablation device 66 during the surgical procedure.

The transmitter 63, located at the distal end portion of the flexible portion 61 outputs a signal indicative of the location of the distal end of the device 60 within the nucleus 10. In this example of the device, the receiver 64 is also located within the nucleus 10, although it will be appreciated that the receiver 64 could be located external of the body of the subject. An example of a suitable mode of transmission in the present example is infra-red transmission.

The position of the transmitter 63 relative to the receiver 64 can be processed by an external processor so as to allow generation of an internal map of the nucleus 10. Transmission of the signal from the transmitter 63 can be continuous, intermittent or user-operated. The user can position the distal end of the device 60 at a position within the nucleus 10, with the aid of the optical camera 65 and externally operate the transmitter 63 so as to determine the coordinates or position of the transmitter 63. Multiple transmissions at various locations along the periphery of the nucleus 10 allow development of a map or visual representation that is indicative of the volume and geometry of the nucleus 10.

The map or visual representation of the nucleus 10 output by the processor can be compared with pre-obtained or simultaneously images of the nucleus from various imaging techniques, such as X-ray, C-T, ultrasound and MRI. Further to this, the image may be overlayed with the map of the nucleus to allow ready determination of the degree of ablation and/or monitoring of the position of the device 10.

Figure 9 is a flow chart of representative of a system that uses the date of device 60. The system shown in Figure 9 also provides visual monitoring of the ablation device 66 by the optical camera 65, and visual monitoring of the portion of the nucleus being ablated and assessment of tissue by the optical camera 62.

A system incorporating such features enables a surgeon to assess the interior space of an intervertebral disc of a subject and to be provided with information as where a surgical instrument is located within the intervertebral disc. Furthermore, data indicative of the internal geometry of the intervertebral disc of subject provided by such a system allows selection of an appropriately sized implant for nuclear pulposus replacement

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this first day of October 2002

Spinemed Australia Pty Limited
Patent Attorneys for the Applicant:

F B RICE & CO

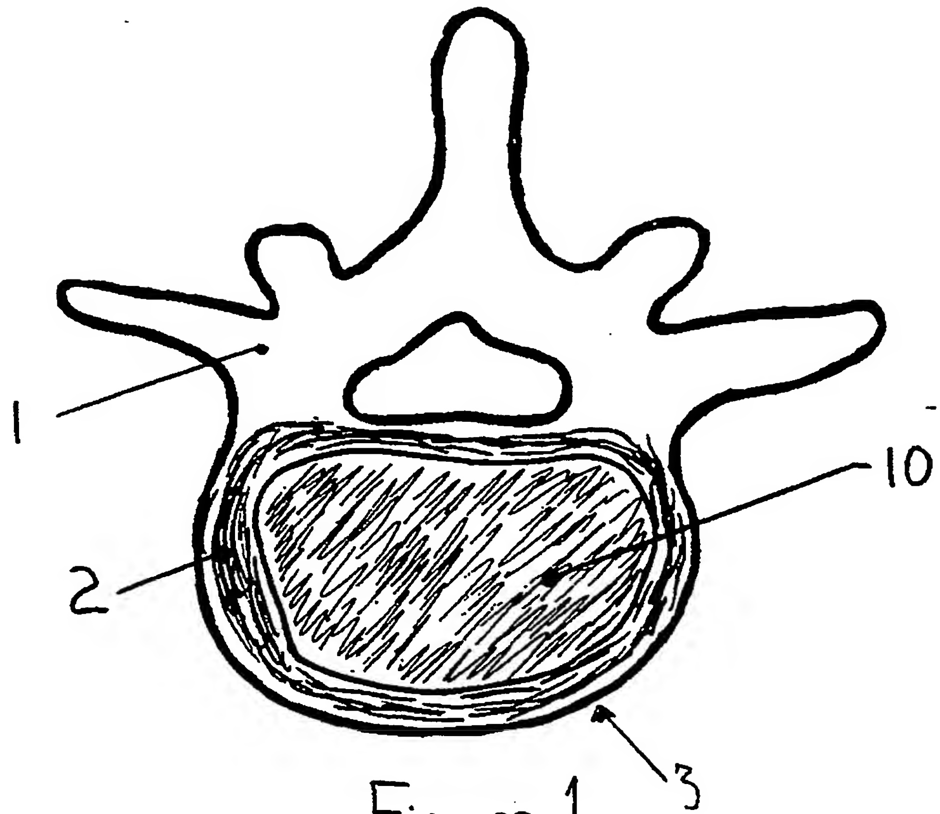

Figure 1

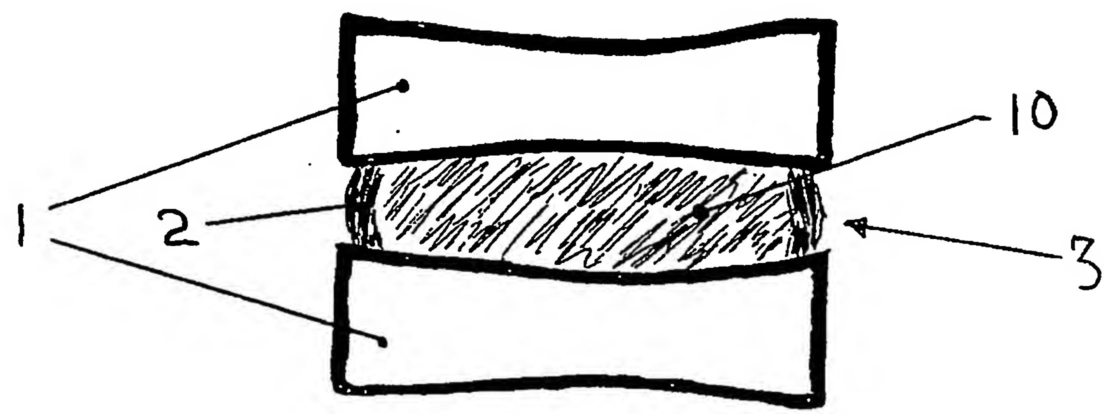

Figure 2

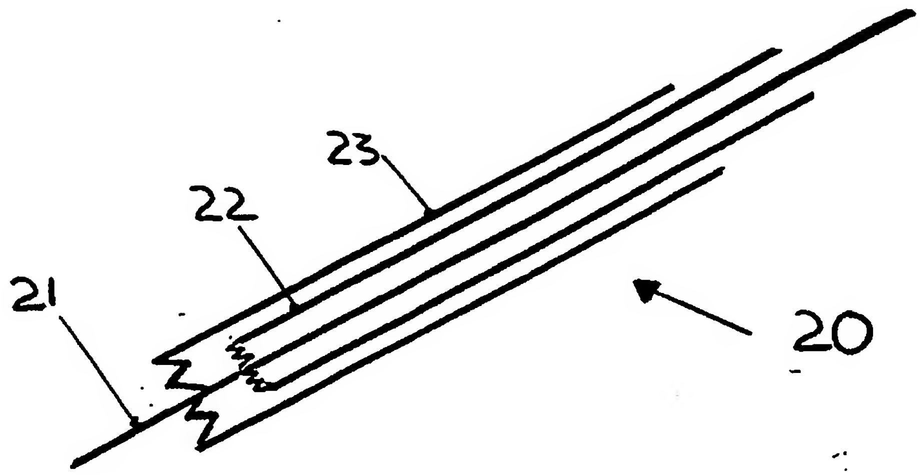

Figure 3

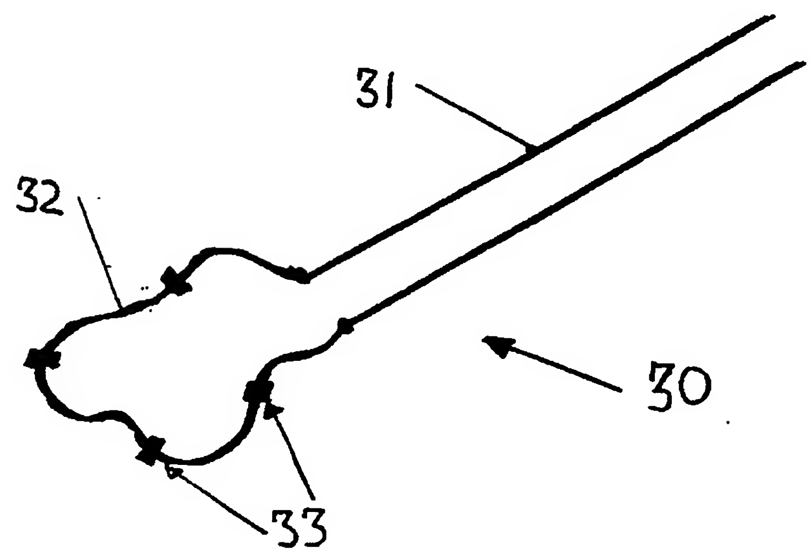

Figure 4

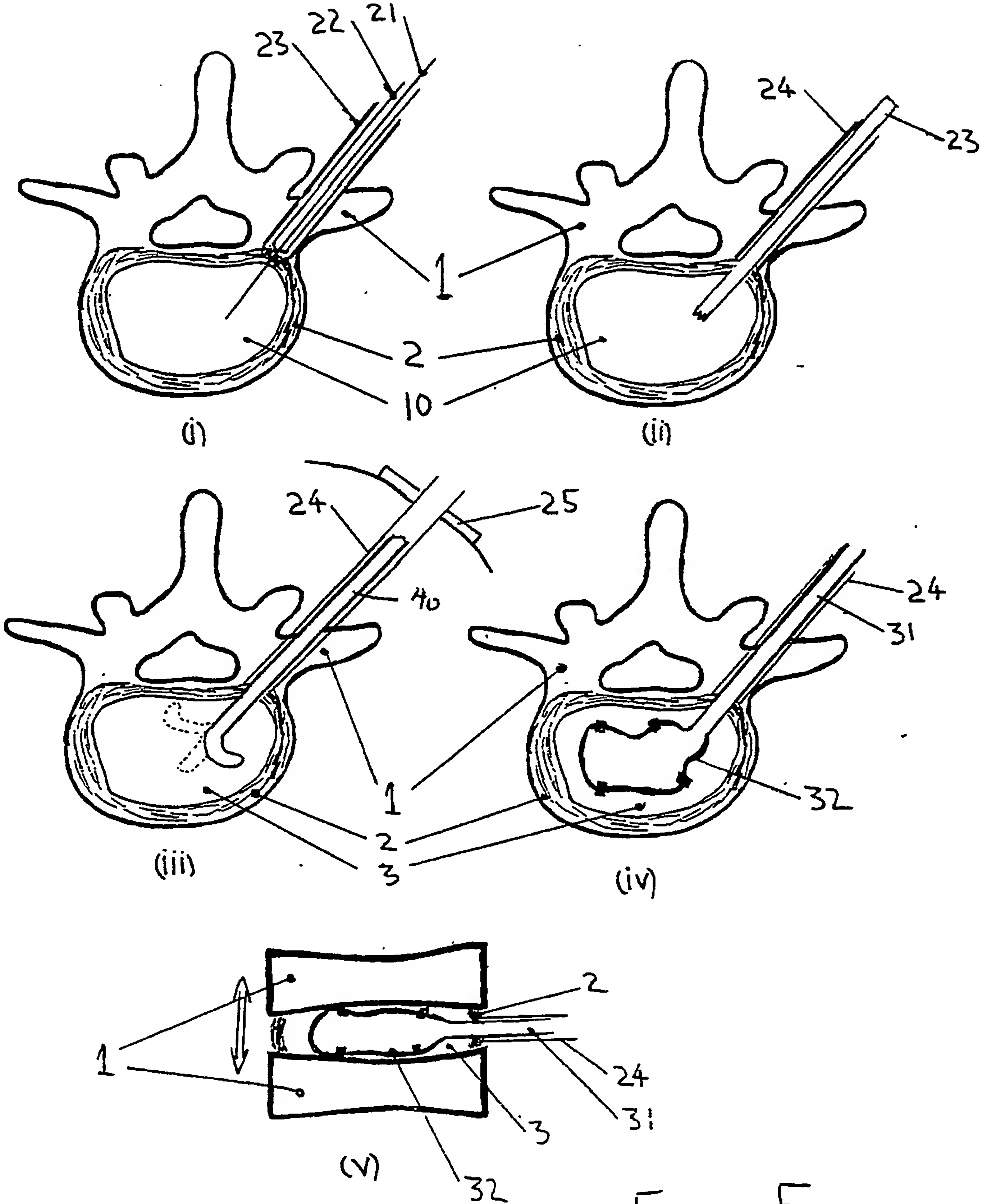

Figure 5

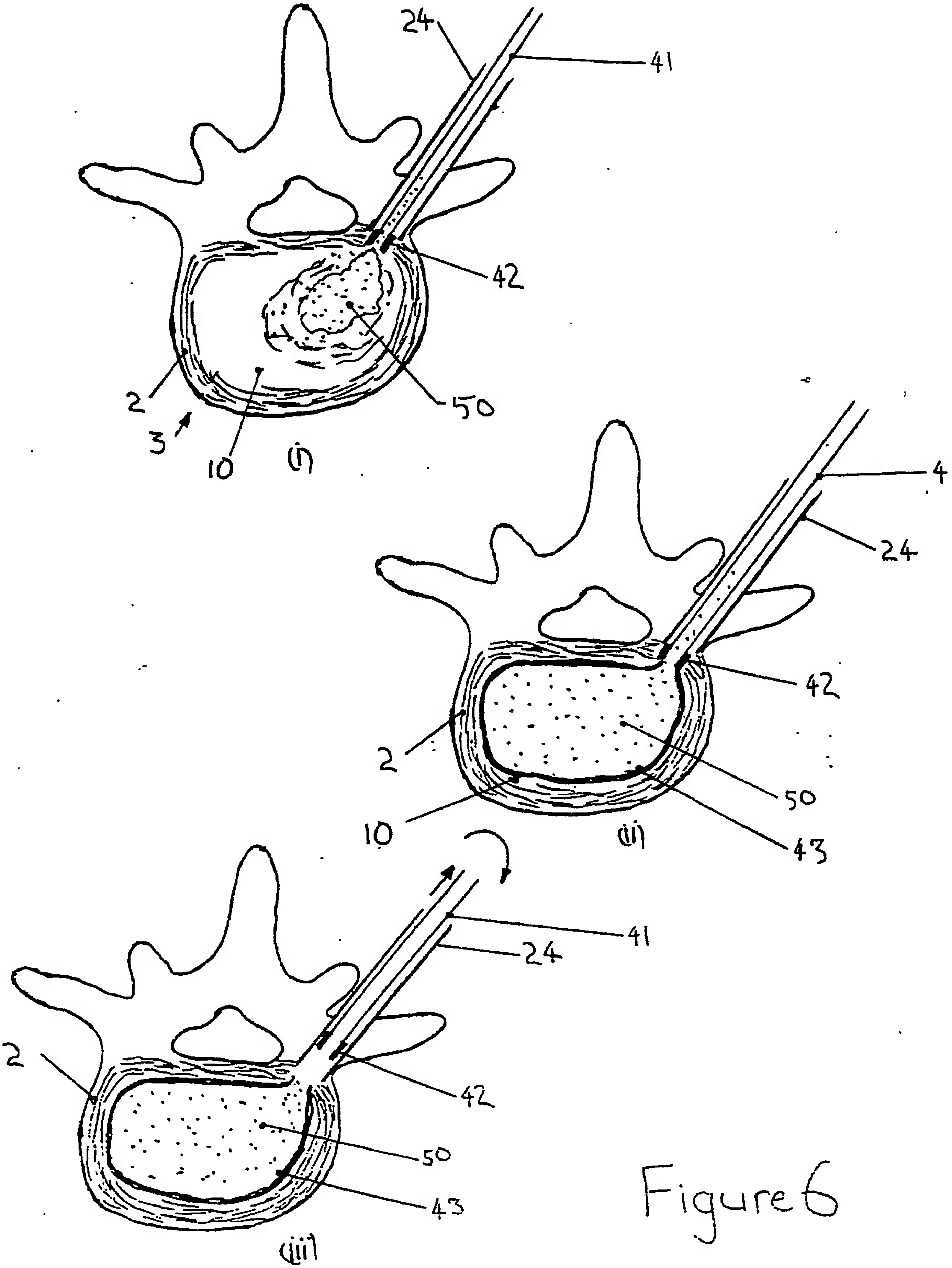

Figure 6

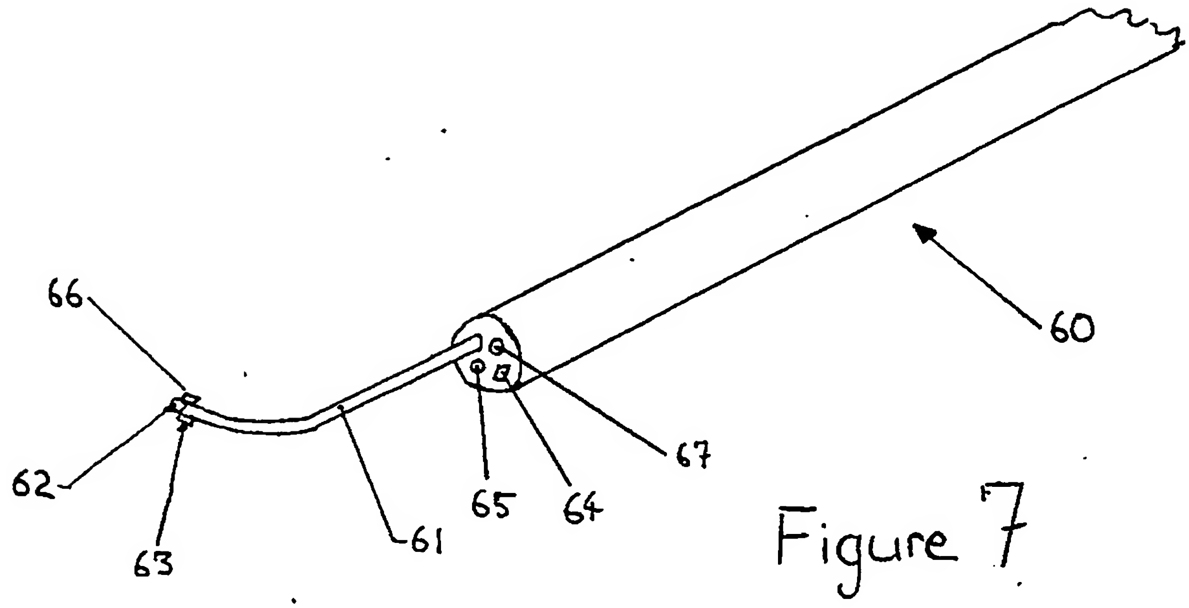

Figure 7

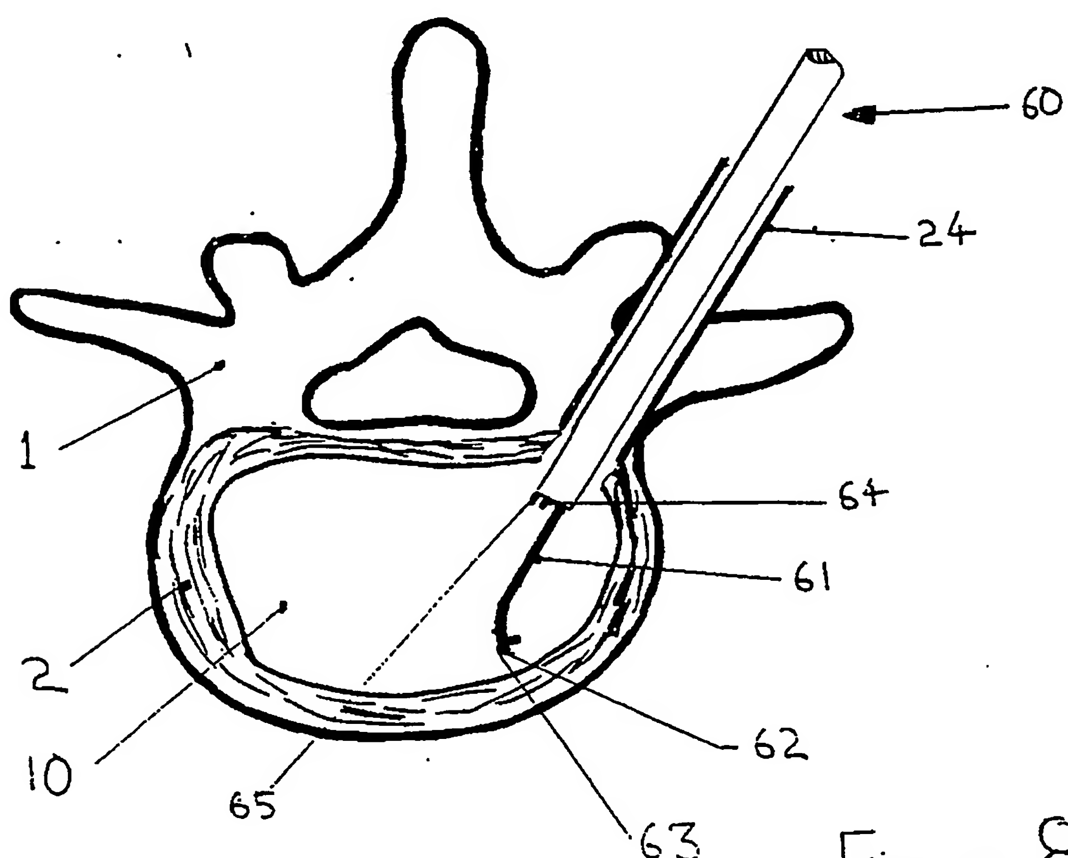

Figure 8

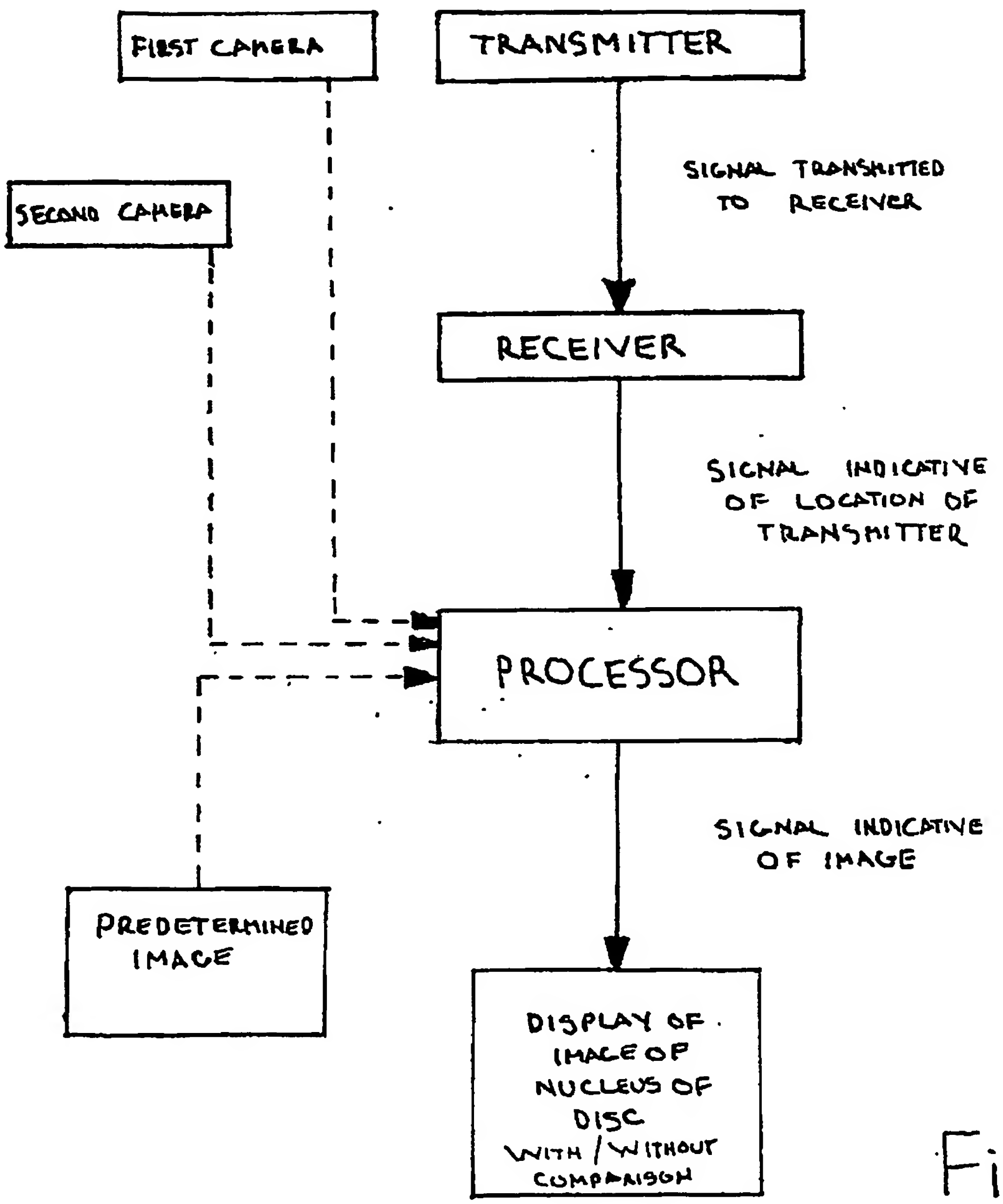
FIRST CAMERA
TRANSMITTER
SIGNAL TRANSMITTED TO RECEIVER
SECOND CAMERA
RECEIVER
SIGNAL INDICATIVE OF LOCATION OF TRANSMITTER
PROCESSOR
SIGNAL INDICATIVE OF IMAGE
PREDETERMINED IMAGE
DISPLAY OF IMAGE OF NUCLEUS OF DISC WITH / WITHOUT COMPARISON

Figure 9